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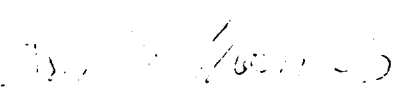
April 19, 1996

Frank Hawkins  
Chairman, U.S. Executive Committee, JCCRER  
Director  
Office of International Health Studies  
EH-63, 270 CC  
U. S. Department of Energy  
19901 Germantown Road  
Germantown, MD 20874-1290

Dear Mr. Hawkins:

Enclosed please find our proposal for the "Plan for Long-term Russian-American Collaborative Epidemiologic Program: Stochastic Effects of Environmental Radiation Exposure in Populations Living Near the Mayak Industrial Association," to be conducted under the auspices of the agreement on radiation effects between the U.S. and the Russian Federation. We are submitting this for review by the Executive Committee and the Scientific Review Group. If you have any questions about the proposal, please feel free to contact me.

Sincerely,

  
Terry L. Thomas, M.S., Ph.D.  
U.S. Leader, Project 1.2  
Associate Professor and Director  
Division of Epidemiology and Biostatistics

cc: Dr. Kossenko, URCRM  
Dr. Hoffman, GWU



**Plan for Long-term Russian-American Collaborative Epidemiologic  
Program  
Stochastic Effects of Environmental Radiation Exposure in Populations  
Living Near the Mayak Industrial Association**

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**Plan for Long-term Russian-American Collaborative Epidemiologic  
Program  
Stochastic Effects of Environmental Radiation Exposure in Populations  
Living Near the Mayak Industrial Association**

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## Abstract

Under the auspices of the "Agreement on Cooperation in Research on Radiation Effects for the Purpose of Minimization of Consequences of Radioactive Contamination on Health and the Environment" signed on January 14, 1994 by the governments of the United States and the Russian Federation, U.S. and Russian scientists will conduct joint collaborative environmental and epidemiologic research. The operation of the Mayak Industrial Association in the South Ural mountains resulted in prolonged exposures to populations living in areas affected by normal plant operations and by releases from accidents. One of the projects approved under the Agreement was the development of a long-term collaborative epidemiologic program to study populations exposed to environmental contamination resulting from Mayak operations.

The proposed program will evaluate mortality and cancer morbidity among persons living in the vicinity of the Techa River and the East Ural Radioactive Trace, and will lay the groundwork for continued follow-up and future collaborative studies of these unique cohorts. Several tasks are proposed as feasibility efforts to develop procedures for vital status follow-up, to determine completeness of information, to identify appropriate comparison populations, and to validate cancer diagnoses. The Ural Research Center for Radiation Medicine (URCRM) has assembled a well-organized data base for the purposes of conducting epidemiologic studies of radiation-related health risks under the unique conditions of chronic exposure in the South Urals at a wide range of doses. This data base will form the basis for the proposed investigation. Limitations are that follow-up is complete only through 1983 for most of the study subjects, a large number of subjects are lost to follow-up, and appropriate comparison cohorts have not been identified.

The East Ural Radioactive Trace (EURT) cohort is composed of residents of Chelyabinsk Oblast who lived in areas contaminated after a 1957 accident at Mayak. The proposed collaborative effort will verify completeness of the cohort, trace lost to follow-up, determine the feasibility of obtaining cancer morbidity information, determine the best approach for calculating doses for the cohort, and determine the feasibility of identifying an unexposed comparison population. The Techa River cohort includes persons residing in villages adjacent to the Techa River downstream from the Mayak production plant who were exposed to routine discharges from the plant during the period 1950 through 1952. The present study will complement an ongoing project being conducted by the National Cancer Institute, which is limited to an evaluation of cancer mortality through 1992. A long-term collaborative epidemiologic program will be developed to continue follow-up of the Techa River Cohort beyond 1992, to determine the completeness and validate cancer morbidity information and to evaluate mortality from non-cancer health outcomes. Continued follow-up procedures and data analysis plans will be prepared for both projects based on success of pilot efforts.

## **I. Introduction**

On January 14, 1994, the Government of the United States and the Government of the Russian Federation signed the "Agreement on Cooperation in Research on Radiation Effects for the Purpose of Minimization of Consequences of Radioactive Contamination on Health and the Environment". Under the auspices of this agreement, U.S. and Russian scientists will conduct joint collaborative environmental and epidemiologic research. Under the terms of the agreement the Joint Coordinating Committee for Radiation Effects Research (JCCRER) was formed to implement the Program of Cooperation. At the first annual meeting of the JCCRER held October 24-25, 1994, three primary areas of cooperation identified were 1) Medical Aspects of Radiation Exposure Effects on the Population; 2) Research on Medical Consequences of Personnel Exposure to Radiation; and 3) Information Technologies in Research on Radiation Effects and Decision-Making Support. The JCCRER tasked its Executive Committee (EC) with identifying and approving pilot projects to be implemented under the program of cooperation during the year following the first JCCRER meeting.

The EC approved three projects under area 1.2 entitled "Risk Estimation for the Deterministic and Stochastic Exposure Effects and the Results of Actual Observations of the Population Health in the Region of the Industrial Association 'Mayak.'" These are: a) physical preservation of existing data; b) evaluation of cancer mortality in relation to radiation exposure among persons living in the vicinity of the Techa River; and c) development of a long-term Russian-American collaborative epidemiologic program for studying the stochastic effects of environmental radiation exposure in populations living near the Mayak Industrial Association. Several milestones were identified for each project to be completed during the pilot implementation phase following the first JCCRER meeting. These included conducting an inventory of existing records and data bases, determining record quality, developing a plan for data preservation, developing methods for determining vital status of exposed cohorts and for identifying unexposed comparison cohorts, reviewing the literature on past epidemiologic studies relevant to these populations, and developing a bibliographic data base. These milestones were successfully completed by the Project Research Team and results are summarized in the Final Report of the Project Implementation Phase (1).

This proposal is for a long-term Russian-American collaborative epidemiologic program to conduct follow-up and to evaluate mortality and morbidity among persons living in the vicinity of the Techa River and the East Ural Radioactive Trace. An ongoing three-year study of the Techa River cohort is being sponsored by the National Cancer Institute. The effort proposed here will complement the NCI study, which is limited to analyzing cancer mortality among the Techa River cohort as of 1992 and determining the most appropriate



comparison group for study. The present project will also lay the groundwork for continued follow-up and future collaborative studies of this unique cohort. This project will conduct epidemiologic follow-up to evaluate mortality and morbidity among members of a second cohort consisting of persons living in the vicinity of the East Ural Radioactive Trace.

## **II. Specific Objectives**

The primary objective of this long-term collaborative epidemiologic project is to assess health risks due to long-term chronic exposure to ionizing radiation. Mortality and cancer morbidity will be evaluated in two populations exposed to environmental radiation contamination. Regional and national mortality rates will be used for external comparison purposes; internal comparisons will use the lowest exposure category as the referent. The feasibility of assembling appropriate non-exposed comparison cohorts will be assessed.

### **A. East Ural Radioactive Trace Cohort**

Specific aims for the East Ural Radioactive Trace cohort are:

1. Evaluate risk of mortality from cancer and other causes of death among the East Ural Radioactive Trace Cohort.
2. Collaborate with scientists from project area 1.1 to develop estimates of individual doses for the EURT cohort.
3. Determine the feasibility of assembling an unexposed comparison cohort.
4. Develop a structure for future follow-up of the cohort.

### **B. Techa River Cohort**

Specific aims for the Techa River cohort are:

1. Evaluate risk of mortality from non-cancer causes of death among the Techa River Cohort.
2. Collaborate with scientists from project area 1.1 to develop estimates of individual doses for the Techa cohort.
3. Determine the feasibility of obtaining cancer morbidity data and validating cancer diagnoses for the Techa River Cohort.

4. Develop a structure for future follow-up of the cohort.

Several tasks are proposed as feasibility studies to develop procedures for follow-up, to determine completeness of information, and to validate diagnoses.

### **III. Background and Significance**

#### **A. Background**

The Mayak Industrial Association, located in the South Ural Mountains began operation in 1948 and was the first Russian site for the production and separation of plutonium. During the early days of operation, technological failures resulted in the release of large amounts of waste into the Techa River. There were also gaseous releases of radionuclides. Mayak operations resulted in prolonged exposures to populations living in areas affected by normal plant operations and by releases from accidents. Beginning in the fall of 1949, liquid radioactive wastes from the Mayak nuclear facility were discharged into the Techa/Iset river system and resulted in radiation exposure to residents of the riverside villages. Due to the contamination, 124,000 persons who lived on the banks of the Techa and Iset Rivers were exposed to varying levels of radioactivity. These individuals were exposed to external gamma radiation and long-lived radionuclides. About 25% of the release activity consisted of  $^{137}\text{Cs}$  and  $^{90}\text{Sr}$ , and exposures between 1950 and 1952 were reported to be the highest due to massive discharges from Mayak during that period. The Urals Research Center for Radiation Medicine (URCRM) created a registry of persons born in 1949 or earlier who lived in the villages on the Techa River during the period of highest exposure.

A total of 26,425 persons were identified as being eligible for inclusion in the Techa River cohort. The average effective dose equivalents were estimated to be from 0.074 Sv to 1.4 Sv, and the average bone marrow doses were estimated to be from 7.5 to 164 cGy. Between 1953 and 1961, a total of 7,500 residents of these villages were resettled in villages further away from the Techa. Another 12,000 persons were identified as residents who didn't live in Techa villages between 1950 and 1952 but moved into one of the exposed but not resettled villages after 1952. Approximately 20,000 progeny of exposed parents were identified. The progeny were identified on the basis of whether or not the father, mother or both parents were exposed. More than 3,000 individuals were identified as being exposed in-utero. Information contained in the registry includes: unique identification number; family name; date of birth; gender; place of residence at exposure; current address; and date of last address.

In September 1957, a thermal explosion in a liquid radioactive waste storage tank located at the Mayak production facility resulted in widespread radioactive

contamination north and east of the plant. The radioactive trace which was formed after the explosion, affected a number of rural settlements in Chelyabinsk, Sverdlovsk. and Tyumen Oblasts. Twenty-two villages located along the axis of the trace were evacuated within 10-250 days after the explosion. About 10,000 persons were evacuated from this part of the trace. Residents of the village of Metlino, located on the Techa River (and whose residents were also included in the Techa River cohort) were relocated once again. Follow-up of residents in the EURT cohort began in 1958. At this time, the Techa River cohort investigation was suspended. Physical examinations of the evacuated residents of the trace was initiated. In the EURT area within Chelyabinsk Oblast 20,000 people (of this number 8,000 were evacuated) received exposures ranging from 10 to 900 mSv. The radiation doses to bone marrow were estimated to be from 30 to 4,000 mSv. Approximately 6,000 residents of the Trace areas were examined between 1959-1961. Hard copies of the examination records are currently stored at URCRM. Eligibility for inclusion in the exposed cohort was based on the Mayak compensation lists. Residents had to be living in the evacuated territories on September 29, 1957 or had to be a resident of adjacent exposed but non-evacuated villages on the same date to be eligible for inclusion in the study cohort. The relocation lists were used as the basis for developing the EURT Registry. Tax books were also used and cross-checked with the compensation lists to determine study eligibility. Approximately 8,000 evacuated residents and 12,000 residents of the non-evacuated area currently comprise the EURT cohort. An additional 9,000 progeny of the exposed EURT cohort members have been identified but not followed.

## **B. Significance**

Other populations exposed to chronic ionizing radiation include those exposed to environmental exposures from nuclear power generation, fallout from nuclear weapons testing, and environmental exposures from nuclear weapons production processes.

Several studies have been conducted of cancer mortality and morbidity in populations residing in the vicinities of nuclear power plants (2-7). These studies were based primarily on population rates of all cancers and for selected sites such as leukemia. Distance from the reactor or county of residence was used as a surrogate for radiation dose in all studies but one (6). In the study conducted by Hatch et al., of radiation exposures from the Three Mile Island accident, atmospheric dispersion models were developed and validated against measurements from off-site dosimeters (6). Taken as a group, the results of these studies provide no evidence of increased cancer rates associated with low-level exposures to ionizing radiation from nuclear power generation. Methodologic problems with these studies include the lack of individual dosimetry, limited statistical power, and little or no information on other factors which may influence

cancer rates. Jablon et al. evaluated county-based cancer mortality rates for the years 1950 through 1984 in populations residing around 52 civilian nuclear power plants and 10 Department of Energy nuclear reactors (7). Counties in which the reactors were located and adjacent counties were considered to be exposed while counties located further away were considered as comparison counties. Cancer mortality rates for 15 selected sites were compared between exposed and comparison county for each reactor and for pre- and post-operational time periods. The results from this study indicated no association between residence in a county with a nuclear reactor and increased cancer mortality rates. The study was limited by the lack of individual radiation doses. A study was conducted in France which investigated leukemia mortality in persons under the age of 25 who resided around 13 French nuclear reactor sites (8). The number of leukemia deaths did not differ from that expected based on population rates. Leukemia rates did not differ by gender, age, and distance from the reactor.

Two studies on the impact on childhood leukemia rates in the wake of the 1986 Chernobyl explosion have been reported, one in Sweden and one in Finland (9,10). Both studies analyzed leukemia rates among children under the age of 15 years in the most heavily contaminated areas of Sweden and Finland and compared these rates with those in other parts of the countries where the contamination was substantially lower. No significant differences in leukemia mortality rates were found to be associated with radioactive contamination from Chernobyl in either country.

Several studies have been conducted of health effects in populations exposed to radioactive fallout due to atmospheric and underground testing of nuclear weapons (11-15). A case-control study of leukemia was conducted in Utah (11). Estimated absorbed doses were calculated for all case and control subjects (12). The median bone marrow doses for all case and control subjects was 3.2 mGy with the estimated maximum mean dose being 29 mGy. In the case-control study, 1117 persons who died of leukemia and 5330 deceased controls were selected for study. A weak association between bone marrow dose and all cell types of leukemia was observed. Significant dose-response trends for excess leukemia risk were only found for certain leukemia cell type, ages, and times after exposure. The greatest excess risk was observed in persons in the highest dose group who had acute leukemia, were younger than 20 years of age at first exposure, and who died before 1964. A retrospective cohort study of thyroid disease associated with exposures to fallout radioiodines was conducted in Utah, Nevada and Arizona (13,14). Individual thyroid gland doses were calculated based on pathway analysis of fallout radioiodines and consumption patterns of milk (14). The mean absorbed dose to the thyroid ranged from 13 mGy to 170 mGy. Ten children had thyroid doses exceeding one Gy. A total of 2,473 persons were clinically evaluated for thyroid disease. A statistically significant excess of thyroid neoplasia was observed with the excess

relative risk estimated at 0.7% per mGy. A positive but nonsignificant dose-response trend was observed for thyroid nodules and carcinomas although the numbers of thyroid cancers were very small ( $N = 8$ ) (13).

A study of childhood cancer incidence was conducted in Kazakhstan (15). Associations between cancer incidence rates and distance from the three former Soviet nuclear weapons test sites in Semipalatinsk and Pavlodar were analyzed. Distance from the three test sites (one site was an "atomic lake" created by four nuclear explosions in 1965) was used as a surrogate for radiation exposure. Cancer rates in children under the age of 14 between 1981 and 1990 were evaluated in the four zones around the test sites. The risk of acute leukemia rose significantly with increasing proximity to the test sites. The relative risk of leukemia for those living within 200 km of the test sites compared with persons living  $> 400$  km was 1.76. Individual radiation doses were not calculated and the rates of cancer may have also been influenced by ethnicity and environmental chemical pollution.

A number of studies have been conducted of the possible association between radiation exposures as a consequence of nuclear weapons production and increased cancer morbidity and mortality, principally childhood leukemia. The majority of these studies have been conducted in the United States or the United Kingdom, and most are of the ecologic correlational design where changes in cancer rates were analyzed as a function of distance from the various weapons processing plants. None of the studies calculated individual radiation doses. The results of these studies have been thoroughly summarized in a review by Shlein et al. (16). The results of the studies in the main have supported no apparent increased risk of cancer morbidity and mortality associated with the levels of environmental ionizing radiation exposures expected of these types of operations. Many of the studies, however, were limited by inadequate statistical power, so that small increases in risk were unlikely to be detected. Also, uncertainties and misclassification in radiation exposures limit the interpretation of these data.

Radiation exposures estimated for subjects in the reviewed studies were, in general, much lower than those for individuals in the URCRM registry. The exposure situations that existed along the Techa and Iset rivers and in the East Ural Radioactive Trace provide a unique opportunity to evaluate the long-term health effects of chronic exposure to environmental radiation in two large populations. In addition, this study will be enhanced by a parallel dose-reconstruction study which will estimate individual doses for each study subject.

#### **IV. Preliminary Studies**

A computer-based individualized registry of exposed people was established at the Urals Research Center for Radiation Medicine (URCRM) to conduct long-

term follow-up studies of the health of the exposed populations. Data on mortality, cancer morbidity and other health outcomes have been collected by URCRM for more than four decades. Medical records have been preserved both on paper and in computer files. Death certificates of people exposed over 34-42 years since the beginning of the exposure are collected in the Death Registry, and cancer cases registered during the same period are stored in the file "Cancer Registry". These information sources constitute the basis for determining the long-term health effects of environmental radiation exposure.

Results from analyses of the registry data were published in a series of articles (17-26). Exposure dose assessment was based on: a) accumulation of external doses using values of on-site gamma-exposure levels and the residents' life styles; b) individual in vivo measurements of Sr-90 body contents in whole body counter SICH-9.1 for 14 thousand residents exposed in the Techa riverside villages. The leukemia death rate was elevated for the cohort exposed on the Techa. Using a relative risk model, the risk of leukemia was estimated to be 0.85 per 10,000 person-years/Gy, which is compatible with the respective values for A-bomb Life Span Study (LSS) cohort. The absolute risk value was estimated to be 0.45-1.1 cases per 10,000 person-years/Gy, which was about 3-5 times lower than the corresponding estimate obtained from the follow-up of atomic bomb survivors. A higher cancer mortality from certain types of solid cancer (cancer of the esophagus, cancer of cervix uteri) was noted for the cohort exposed on the Techa, and there was a slightly increased death rate from congenital anomalies among those exposed in utero. Preliminary analyses have indicated no increase in the rate of cancer among those exposed in the EURT area as of the present time; however, follow-up is incomplete for about one-third of the cohort, and vital status for the remainder of the cohort is complete only through 1983.

URCRM has assembled a well-organized data base for the purposes of conducting epidemiologic studies of radiation-related health risks under the unique conditions of chronic exposure in the South Urals at a wide range of doses; however, the earlier analyses had several limitations which will be addressed by the present study. These include: a) follow-up for these studies was only completed through 1983; b) lack of a fixed comparison group; c) loss of a significant number of exposed people to follow-up; and d) dosimetry estimates need substantial refinement.

## **V. Research Design and Methods**

### **A. Study Population**

#### **1. East Ural Radioactive Trace Cohort (EURT)**

The definition of the East Ural Radioactive Trace Cohort is the following: anyone who resided in the area of Chelyabinsk Oblast covered by the Trace at the time of the accident. For the EURT cohort, URCRM scientists used the information contained in tax books and resettlement and compensation lists (Mayak books) to determine the basis for completeness and inclusion in the registry. A total of about 20,000 individuals are included in the cohort. Residents had to be living in the evacuated territories on September 29, 1957 or had to be a resident of adjacent exposed but non-evacuated villages on the same date to be eligible for inclusion in the study cohort. Identification and follow-up through 1983 is complete for 8,083 residents who were evacuated from the trace. About 12,380 residents lived in the adjacent non-evacuated areas. Follow-up is complete through 1983 for 8,380 of these individuals, and approximately 4,000 are lost to follow-up.

#### **2. Techa River Cohort**

The definition of the Techa River Cohort is the following: any person residing in a village adjacent to the Techa River downstream from the Mayak production plant to where the Techa enters the Iset River, a distance of 237 kilometers. This area includes persons residing in both the Chelyabinsk and Kurgan Oblasts in the following five rayons: Krastnoarmeysky, Kunashksky and Kaslinsky in Chelyabinsk Oblast, and Katayaky and Dalmatovsky in Kurgan Oblast. To be eligible for inclusion, a person had to reside in one of these villages for at least one month between 01 January 1950 through 31 December 1952. Although persons living in these villages were likely exposed to radiation from Mayak prior to 1950, the greatest radiation exposures occurred from 1950 through 1952. The registry assembled and maintained by the URCRM for the past 40 years will be used as the basis for identifying study subjects for this project.

An estimated 1,700 persons are included in both the Techa and EURT cohorts. This group consists primarily of residents of the village of Metlino, who were resettled twice, once after 1952 and again after the 1957 accident at Mayak.

#### **3. Sources of URCRM Registry Data**

The following sources of information were used to construct the URCRM registry which contains information on subjects in both cohorts:

**a. Relocation lists**

Entire villages were resettled due to the contamination along the Techa River. In the 1950's, the Regional authorities prepared lists of families and family members who were evacuated. Information contained in the resettlement books included family name, address, year of birth, profession, amount of compensation, and village of resettlement (or if they refused to be resettled). The relocation books were not available for all villages. The existing books were checked against other resources to determine their completeness and how comparable the information was contained in the different sources.

**b. Internal passports**

Each citizen of the former Soviet Union was required to maintain an internal passport which included information on name, date and place of birth, place of residence, and passport number. This system of registration was relatively complete except for certain rural areas where residents didn't have internal passports until the end of the 1960's. The internal passport was used to track the comings and goings of residents. Whenever a resident traveled to another village or city, they had to register their passport at the local militia office. The passports were used to confirm place of residence for cohort identification.

**c. Tax books**

Every family residing in an administrative area was included in the local tax book. Information contained in these books included for each family: family name, names of all of the members of the family, relationships, birth dates, ethnic group, school, size of house and list of possessions. The tax books were maintained and administered by the Rayon authorities. They were completed by members of the local village Soviet council. Every three years, a new tax form was completed and information in the books was updated. Tax books were complete for the years 1950 through 1983. However, there were missing tax books for some villages in the Techa River cohort.

**d. Detailed military maps**

Detailed maps prepared by the military were used to identify cottages and private homes in the study areas. Study investigators used these maps to go to the resettlement areas to interview residents, show them the maps, and ask them to identify their house and those of their neighbors. Many residents were located in this fashion. The information from this source was compared to that in the medical records.



A linked record was prepared containing information from the following sources:

- a) tax books
- b) military maps
- c) interviews
- d) medical records
- e) Mayak resettlement books

Completeness of the Techa River exposed cohort was determined by comparing the pre-1950 tax books for villages along the Techa with tax books for the 1950-52 period. During the first stage of the study, the cohort excluded teachers and physicians who worked in the villages but did not reside there. The study investigators went to the regional administration office to determine who was sent to work in the villages. Children who resided in two orphanages in 1950-52 were identified through records maintained at the regional administration office. In 1993, the regional government decreed that a list should be prepared for all resettled persons so that they could receive certificates of relocation. The URCRM registry lists were compared with the government lists to determine completeness. This work continues, and to date, six of the 13 lists have been completed. The government relocation lists contain family name, date of birth, internal passport number, and reason for compensation regardless of where they live. The lists were completed only for those persons still alive as of the end of 1993. Based on assessment of multiple sources of information, especially comparing the pre-1950 tax books with the residents enrolled in the cohort, the URCRM investigators believe that the Techa registry is almost 100% complete.

#### **e. Books for registered evacuees**

In 1992, the Russian Federation passed a law entitling citizens accidentally exposed to radiation to governmental aid. The passage of this law ("On Social Support to Citizens Exposed to Radiation") was followed by the President's decree on its application to individuals exposed from the activities of the MAYAK Industrial Association. Commissions were established to create registries of evacuated persons eligible to receive the certificates. The registries of eligible citizens included surname, given name, patronymic, current address, passport number, a list of documents substantiating the applicant's right to a certificate, identification number, and certificate number. Xerox copies of these books will allow the URCRM staff to identify the place of residence of exposed and evacuated people at the time of issuance of certificates (about 1993, 1994). In all, 7500 thousand residents were evacuated from the Techa riverside villages between 1953 and 1961. Evacuees were people who lived on the banks of the Techa River from 1950-1952, as well as those who moved to the area later and lived there until

evacuation. Work to match the information in these books has begun, and indicates that the books will be a good source for tracing persons currently lost to follow-up.

URCRM maintains hard copy records and a large computer database containing information collected during the formation of the registry. The hard copy records and computer databases are described in Appendices A and B.

## **B. Data Collection**

### **1. East Ural Radioactive Trace Cohort**

#### **a. Trace lost to follow-up**

In past follow-up efforts, URCRM researchers have used death certificates, local address bureaus, and personal contacts with cohort members and their relatives to determine vital status.

Because there is no Russian registry of deaths that covers the whole country, several sources of death information are used by URCRM to ascertain deaths in their study populations. The primary source is the office of the **regional registrar** (at the rayon level), known as "**ZAGS**," where the death certificates may be retrieved. The second source is the next-of-kin, relatives and friends. Any person who comes to the clinic for an examination is questioned regarding the status of all next-of-kin. Detailed information is collected for each of the relatives for the following items: vital status, residence, health, and place of death if dead. If a study subject is reported to be dead, URCRM will write to ZAGS in the rayon where the person died to obtain a copy of the death certificate.

URCRM has collected approximately 70% of the death certificates for persons who are known to be deceased. The 30% that they are lacking are from people who moved away. For the majority of those who are dead and moved away, URCRM knows where and when they died. When a person leaves the 5 rayons around Chelyabinsk or moves to a new oblast or one of the other independent states, it becomes much more difficult to obtain a death certificate. The majority of the 30% of unretrieved certificates are from deaths in the Chelyabinsk Oblast, but outside the 5 rayons in the Oblast that are routinely searched. The missing death certificates are spread across the entire 33 year period of follow-up, but most are in the later years due to the aging of the population. All death certificates in the five rayons where the EURT and Techa cohorts are located have been collected from 1945 through 1992.

Each person in a region is required to register their passport at the local militia office. The local address bureau officials apply to the militia department to

verify whether a person lives in a particular region or Oblast. The researchers at URCRM have to pay for the new address information. The address bureau will give the current address for people still living in the Oblast and will let the researchers know if a person has moved away; however, forwarding addresses are not available. This office may or may not indicate if a person has died. Tax rolls are also used to ascertain deaths. All the tax rolls were examined for migration and death through 1983. Prior to terminating the use of the tax rolls, URCRM had been making mortality updates once every five years and this was their main source of follow-up.

URCRM researchers have not traced EURT subjects who migrated to distant regions because of the cost in doing so. Vital status determination is complete through 1983 for most of the EURT cohort, but is unknown for about 4,000 people who migrated from the contaminated area. A number of methods and techniques for determining vital status will be analyzed and tested during the first year of the study. Proposed methods for tracing subjects lost to follow-up are: (1) using information from the books listing registered evacuees from the contaminated territories; (2) abstracting information from address registration documents; (3) interviewing relatives; (4) making inquiries at address bureaus; (5) writing to subjects at their last known address. Methods to be used for retrieving death certificates are: (1) computer matching death certificates to the study cohort file; (2) interviewing the next of kin; and (3) making inquiries at the Civil Registrar's Office. A structure will be developed to update vital status at regular intervals (e.g., every two to three years). This will include efforts to locate as many subjects lost to follow-up as possible.

b. Code and computerize death certificate information

About 7,000 death certificates through 1993 have been collected for residents of the five rayons where the EURT and Techa cohorts are located, but have not been matched with the URCRM registry or computerized. These death certificates will be matched with the registry to identify those deaths occurring among members of the EURT cohort. Underlying cause of death will be coded and data from the appropriate death certificates will be key entered and added to the registry.

c. Verify completeness of cohort subjects born after 1957 but still living in contaminated zone

Birth certificates for persons born after 1957 in Chelyabinsk Oblast who are living in the contaminated area will be copied and computerized to verify completeness of that subset of the EURT cohort.

d. Determine feasibility of obtaining cancer morbidity information

A cancer morbidity file has been developed at the URCRM. A 1964 decree issued by the Soviet Ministry of Public Health stated that for all cases of cancer diagnosed by a physician, a special notification form had to be completed. The completed forms were sent to a specialized oncology center located in each Oblast. This center coordinated cancer notification and reporting for every Rayon in the Oblast, and the forms are maintained by the center for a minimum of three years. Each year, scientists from the URCRM visited the oncology centers in Chelyabinsk and Kurgan (until 1970) Oblasts to make copies of the notification forms. This data source may be useful to calculate population rates for cancer for each rayon in the two Oblasts and thus serve as a potential source of an external comparison group. The notification system is approximately 90 - 95% complete. Records for all cancer cases in three rayons of Chelyabinsk Oblast in the Trace area, including the resettled area, are collected on a routine basis and are complete through 1992. Data for residents of Kurgan Oblast are complete only from 1950 through 1970. The names are matched with the list of exposed subjects to determine cancer incidence for the cohort. Cases not exposed may be used as numerators to calculate rates for the unexposed areas.

A one-year feasibility study will be conducted to determine whether cancer morbidity can be determined for the EURT cohort. Information is currently available on cancer morbidity for about 40% of the cohort from two of the rayons, and may be less complete for the third. During the one-year feasibility study, the oncology centers in each rayon will be visited to determine completeness of information on cancers diagnosed among the EURT cohort. All cases of cancer occurring among residents of these rayons will be determined. The names will be matched with the list of exposed EURT subjects. At the time of these visits, the availability of pathological materials (slides, blocks) for validating diagnoses will be determined. Cancer cases ascertained from the oncology centers will also be matched against the roster of deceased subjects to determine whether individuals reported to have died from cancer were recorded by the oncology centers as having cancer. If sufficient information is available to determine cancer morbidity for this cohort, and pathological materials are available to validate diagnoses, detailed procedures for collecting appropriate information and validating diagnoses will be developed. This effort will be conducted concurrently with the effort to validate cancer diagnoses for the Techa River Cohort.

e. Dosimetry

Current dose estimates are based on individual measurements of internal dose for about 50% of the cohort using a whole body counter and on measures of

external dose using gamma dose rate as measured in the air and life style patterns. Dose estimates will be verified and improved using methods developed by the dosimetry team in a parallel project (27). A one-year feasibility study will be conducted prior to a full-scale dose reconstruction effort. The dosimetry team will calculate collective doses for each village, and the epidemiology team will calculate statistical power for detecting excess risk for specific cancer sites. An assessment will be made by the epidemiology-dosimetry project teams at the end of this year to determine the best approach for calculating doses for this cohort. If there is sufficient statistical power, doses to bone, lung, gastrointestinal tract, liver, breast, uterus, brain will be estimated. The contribution of external dose to total dose will be determined. Individual doses are desirable, but for many subjects, group doses will have to be calculated. This task will be completed by the dosimetry team under Project 1.1.

f. Identify unexposed comparison population

A one-year feasibility study will be conducted to determine the best unexposed comparison population. It may be possible to use tax books for a few villages to identify and follow an unexposed cohort. A determination of which villages were actually exposed to routine Mayak plant operations must be made so that they may be excluded from the unexposed comparison population rates. This issue will be addressed by the Project 1.1 dosimetry team.

g. Computerize outpatient card data

Outpatient cards maintained by URCRM have not been computerized and will be key entered. These records contain information that will assist in validating cancer diagnoses and in reconstructing doses for this cohort. The same file structure as that for the Techa River cohort will be used in adding this information to the URCRM registry. All of the existing EURT registry data has been merged with the Techa River cohort, but is in a slightly different format. Data for the EURT cohort will be re-structured to match that of the Techa River cohort.

## 2. Techa River Cohort

Under an ongoing project (1.2b, being conducted by the National Cancer Institute) mortality follow-up for this cohort will be completed through 1992. The three-year NCI study is limited to an evaluation of cancer mortality through 1992 and identification of a suitable comparison cohort. The present study will establish a long-term collaborative epidemiologic program to continue follow-up beyond 1992, and to evaluate cancer morbidity and mortality from non-cancer health outcomes. Some of the activities proposed will be conducted concurrently with project 1.2b,

while others will begin after results are available from the NCI study and from feasibility studies to be conducted under this project.

**a. Concurrent Activities**

**i. Determine completeness of cancer morbidity information**

During the first year of this project, the completeness of current information will be assessed. Cancer cases ascertained to date from the oncology centers will be matched against the roster of deceased subjects to determine whether individuals known to have died from cancer were recorded by the oncology centers as having cancer. All cancer deaths should appear in the mortality file. In addition, the morbidity file should contain more cases of each type of cancer than the mortality file, particularly, for non-fatal types of cancer and those associated with long survival. If information provided by the oncology centers appears to be complete, cancer morbidity information for Chelyabinsk Oblast will be updated during the subsequent two years with the most recent information available. URCRM staff will copy the cancer notifications from the oncology center in Chelyabinsk Oblast and enter the information into the computer data base.

A one-year feasibility study will be conducted to determine the availability and completeness of cancer incidence data for residents of the two rayons in Kurgan Oblast after 1970. A recent review of oncology records in Kurgan Oblast indicates that information is complete for the time periods 1950 through 1970 and from 1981 to 1995. URCRM staff will visit the oncology center in Kurgan Oblast and determine whether complete information on cancers diagnosed between 1970 and 1981 can be retrieved. All cases of cancer occurring among residents of the two rayons in Kurgan Oblast will be determined. The names will be matched with the list of exposed subjects. Those not exposed may be used to calculate morbidity rates for the unexposed.

**ii. Validate cancer diagnoses**

Procedures for validating cancer diagnoses will be developed in parallel with those for the EURT cohort (V.B.1.d). The URCRM has maintained a repository of over 2,000 stored bone and bone marrow tissue samples representing over 1,200 individuals where a hematological illness, not necessarily leukemia, was suspected. These can be used to validate hematopoietic malignancies. A one-year feasibility study will be conducted to determine the availability of pathological materials for validating other cancer diagnoses and to develop procedures for such validation. The feasibility of using tissue slides for validating hematologic and solid tumor diagnoses in Chelyabinsk and Kurgan Oblasts will also be explored. During the

visits to the oncology centers for V.B.1.d above, URCRM will determine the availability of tissue slides and blocks for cancer cases in the Techa River cohort diagnosed after 1950.

**iii. Computerize data necessary to complete dosimetry**

Information on distance of home to the Techa River, consumption of fish from the river, and consumption of river or well water is contained in the outpatient records for approximately 45% of the outpatient records for the Techa River cohort. This information needs to be abstracted from the outpatient records and entered into the computer. Abstract forms will be developed by URCRM staff. The outpatient record for each subject will be obtained from URCRM hard copy files, and information will be entered onto the abstract form. The data will be key entered and placed in the URCRM computer data base.

**~~iv.a~~ Dosimetry**

Current dose estimates are based on individual measurements of internal dose for about 50% of the cohort using a whole body counter and on measures of external dose using gamma dose rate as measured in the air and life style patterns. Dose estimates will be verified and improved using methods developed by the dosimetry team in a parallel project (27). Doses to bone, lung, gastrointestinal tract, liver, breast, uterus, brain will be estimated for each member of the cohort. The contribution of external dose to total dose needs to be determined. This task will be completed by the dosimetry team under Project 1.1 and methods are described in detail in a separate protocol (27).

**b. Future Activities**

**i. Develop structure for continued follow-up for mortality and cancer morbidity**

Past follow-up efforts are described in section V.B.1.a above. URCRM researchers have not traced people who migrated to distant regions because of the cost in doing so. Approximately 3,500 persons from the Techa River cohort are known to have left the area for distant regions. Some people who have moved to other regions still come back to the clinic periodically so the staff at URCRM knows that they're still alive and they are questioned regarding others in their families who may have moved, also.

During the present project, a structure will be developed for updating vital status information and obtaining cancer morbidity information on the cohort at regular intervals every two to three years beyond 1992. Mechanisms identified for

conducting follow-up were identified during the pilot feasibility study include: (1) using information from the books listing registered evacuees from the contaminated territories; (2) abstracting information from address registration documents; (3) Interviewing relatives; (4) Making inquiries at address bureaus; (5) writing to subjects at their last known address. Methods to be used for retrieving death certificates are: (1) computer matching death certificates to the study cohort file; (2) interviewing the next of kin; and (3) making inquiries at the Civil Registrar's Office. Through experience gained from vital status follow-up being conducted through 1992 for the NCI study, the investigators will develop a manual of procedures for continuing follow-up of the cohort. This will include specific procedures for tracing subjects who have migrated or whose vital status is unknown.

### **C. Data Analyses and Statistical Power**

We hope to be able to examine morbidity rates for specific cancer sites by dose, ethnicity, gender, and age for the EURT and Techa River cohorts, mortality from specific cancer sites among the EURT cohort, and mortality from non-cancer causes among both cohorts. In particular, we are interested in morbidity and mortality from all cancers and from leukemia. For each cohort will compare cause-specific numbers of deaths (or incident cases of cancer) observed among the study cohort with the numbers that would be expected based on rates in a suitable comparison cohort, adjusting for calendar period, attained age, and ethnicity. A time-failure multivariate model (28) will be used to evaluate the relationship between radiation dose and cancer mortality (all sites combined and separately for leukemia and other sites of interest), adjusting for the potential confounding effects of attained age, ethnicity, and other factors. Our ability to conduct these analyses is dependent on the success of several feasibility studies that will be conducted during the first year of this three-year project. These efforts include: determining whether cancer morbidity can be validated for both cohorts, evaluating whether efforts are successful in determining vital status for those lost to follow-up, and determining the appropriate comparison populations. Our ability to evaluate morbidity and mortality for specific doses is dependent on the success of the dose reconstruction project. Calculations of statistical power for detecting excess risk of specific cancer sites of interest will be conducted as soon as there is sufficient information on dose and the size of various subgroups of both cohorts. A detailed plan for data analyses will be developed for each cohort and submitted to the Scientific Review Group for review before the third year of the project.

### **VI. Quality Control/Quality Assurance**

Several activities to be conducted under this protocol have been proposed as feasibility studies to ensure completeness and accuracy of existing data and to complete tracing of lost to follow-up. Procedures developed for future follow-up and



validation of diagnoses will take into account the success rates from the various methods employed during the feasibility studies. New data collected during the course of this investigation will be double key entered to ensure accurate data entry. Routine quality control procedures for developing and maintaining the URCRM computer database are described in Appendix B. The current system of checking variable ranges and internal consistency of death certificate data will be reviewed and enhanced as necessary for this study. Steps will also be taken to assess the quality of coding. In particular, information for a 5% sample of subject records will be validated and a 10% sample of death certificates will be recoded and the results compared to data already in the system. Causes of death for deaths from 1950 to 1982 have been coded using ICD-8 codes. These will be recoded to ICD-9 using computer conversion programs. Efforts will be made to validate cancer diagnoses for both the EURT and Techa River cohorts (see V.B.1.d and V.B.2.a.i and V.B.2.a.ii) using medical records, slides, blocks and other available information.

## **VII. Collaborators/collaborating Institutions**

### **A. Overall Project Management**

#### **1. Russian Team - URCRM**

Dr. Mira Kossenko, Principal Investigator

- a. Role: scientific supervision of the research, setting-up of epidemiological tasks, identification of volume and quality of information on cancer mortality for people exposed on the Techa, data analysis, preparation of reports and publications
- b. Percent effort on this project: 25-30%
- c. Other sources of support:  
RFP Number NCI-CP-50507-13 Epidemiologic Studies of the Mayak and Techa River Cohorts in the Russian Federation": 20-25% of time.

Catherine M. Zhidkova, Project Coordinator

- a. Role: delivery of the products required by the Project (progress and final reports) and all required documentation to the EC of the JCCRER by the dates indicated in the Project; prepare official correspondence related to the Project issues related to data sharing involving URCRM DB, information dissemination, intellectual property, copyright translation into English/Russian of scientific reports to be submitted to the EC of the JCCRER

Planning and organization of Project-related visits  
to the URCRM of foreign participants, interpreting

- b. Percent effort on this project: 30%
- c. Other sources of support:  
NCI-CP-50517-13 "Epidemiologic Studies of the Techa  
River and Mayak Cohorts in the Russian Federation":  
20% of time.

Lydia Nikolayenko, Data Base Manager

- a. Role: improvement and updating of the computerized  
data base comprising information on residents  
exposed on the river Techa and the EURT territory  
(registry, migration, death certificates, cancer  
morbidity), selection of sets of information to be  
analyzed, checking information quality.
- b. Percent effort on this project: 30%
- c. Other sources of support:  
RFP Number NCI-CP-50517-13 "Epidemiologic Studies of  
the Mayak and Techa River Cohorts in the Russian  
Federation": 20% of time.

## **2. American Team**

Dr. Terry Thomas, Principal Investigator

Uniformed Services University of the Health Sciences

- a. Role: Technical assistance, support, and collaboration on  
study design and development, data collection; data  
analyses; preparation of reports and publications
- b. Percent effort on this project: 10%
- c. Percent of time committed to other projects: 30%

Dr. Daniel Hoffman, Co-Principal Investigator

The George Washington University

- a. Role: Technical assistance, support, and collaboration on  
study design and development, data collection; data  
analyses; preparation of reports and publications
- b. Percent effort on this project: 10%
- c. Percent of time committed to other projects: 20%

## **B. East Ural Radioactive Trace Cohort**

### **1. Russian Team - URCRM**

The Russian team will be responsible for the day to day management of project activities, including data collection, data entry, and editing. The Russian team will also collaborate with the American team on study design, data collection, and analyses. Members of the Russian team will visit the U.S. each year for small focused workshops and training.

#### **D. Lioudmila Krestinina, Project Director**

- a. **Role:** carrying out studies aimed at radiation effects assessment for people exposed in the EURT area, summarizing the information on death cases for this cohort, assessment of completeness of the registry, preparation of scientific publications
- b. **Percent effort on this project:** 30%
- c. **Other sources of support:**  
RFP Number NCI-CP-50517-13 "Epidemiologic Studies of the Mayak and Techa River Cohorts in the Russian Federation". 20% of time.

#### **Svetlana Nizhegorodova (Epifanova), Computer Programmer**

- a. **Role:** development of software for DB management and supporting problem files
- b. **Percent effort on this project:** 30%
- c. **Other sources of support:**  
RFP Number NCI-CP-50517-13 "Epidemiologic Studies of the Mayak and Techa River Cohorts in the Russian Federation": 20% of time.

3 technical support personnel

## **2. American Team**

The American team will provide technical assistance, support and collaboration on study design, data collection, and analyses. Members of the U.S. team will visit Chelyabinsk a minimum of two times per year to provide technical assistance for ongoing projects and to collaborate in data collection and analyses.

Dr. Daniel Hoffman, Project Director  
The George Washington University

Dr. Terry Thomas, Co-Project Director  
Uniformed Services University of the Health Sciences

Dr. Donna Cragle, Epidemiologist  
Oak Ridge Institute for Science and Education

## **C. Techa Cohort Project Management**

### **1. Russian Team - URCRM**

The Russian team will be responsible for the day to day management of project activities, including data collection, data entry, and editing. The Russian team will also collaborate with the American team on study design, data collection, and analyses. Members of the Russian team will visit the U.S. each year for small focused workshops and training. Specific roles are the following:

Dr. Mira Kossenko, Project Director

Dr. Yevgeniya Ostroumova, Epidemiologist

- a. Role: studies on late effects of radiation for exposed Techa residents, data collection, analysis, calculation of cancer morbidity, risk assessment
- b. Percent effort on this project: 50%
- c. Other sources of support:  
does not participate in other international projects: time spent on Russia-funded projects: 50%

Dr. Nadezhda Gudkova, Epidemiologist

- a. Role: studies of general and cancer mortality for people exposed on the Techa, data collection, analysis
- b. Percent effort on this project: 50%

- c. Other sources of support:  
does not participate in other international projects; time  
spent on Russia-funded projects: 50%

Svetlana Nizhegorodova (Epifanova), Computer Programmer

- a. Role: development of software for data base management  
and supporting problem files
- b. Percent effort on this project: 30%
- c. Other sources of support:  
RFP Number NCI-CP-50517-13 "Epidemiologic Studies of  
the Mayak and Techa River Cohorts in the Russian  
Federation": 20% of time.

4 technical support personnel

Oncological Center, Kurgan Oblast  
1 person

Oncological Center, Chelyabinsk Oblast  
1 person

## **2. American Team**

The American team will provide technical assistance, support and collaboration on study design, data collection, and analyses. Members of the U.S. team will visit Chelyabinsk a minimum of two times per year to provide technical assistance for ongoing projects and to collaborate in data collection and analyses.

Dr. Terry Thomas. Project Director  
Uniformed Services University of the Health Sciences

Dr. Daniel Hoffman. Co-Project Director  
The George Washington University

Dr. Donna Cragle. Epidemiologist  
Oak Ridge Institute for Science and Education

## VIII. Human Subjects Considerations

A registry containing medical and follow-up information on members of the EURT and Techa River cohorts is maintained by the URCRM and was compiled from several sources as described above. In addition, subjects with hematological disorders have been examined and treated at the URCRM. All hard copy records are maintained by the URCRM in locked file areas. Access is provided only to research and medical staff as necessary. Computer data bases are password protected, and access to various modules is provided to researchers and medical staff of the URCRM only on an "as needed" basis. Identifying information is maintained only for the purposes of tracing cohort members and for maintaining patient treatment records. Each subject has been assigned a unique systemic number. To protect confidentiality many of the modules in the computer data base have been stripped of all identifying information except for the systemic number which is used to link data from the various modules. **There will be no contact with study subjects during the course of this investigation except during tracing of lost-to-follow-up or during routine clinic visits. Tracing may involve contacting some of the subjects or their next-of-kin only for the purpose of determining current vital status.** All files used for epidemiologic analyses will be stripped of identifying information except for the unique systemic number. Reports of results will contain totals, averages, and other statistics and will not contain any information which would allow the identification of any individual.

This project plan along with other appropriate documentation will be submitted to **Institutional Review Boards** at the Uniformed Services University of the Health Sciences and the George Washington University for approval of research involving human subjects. On the Russian side documentation will be submitted to the Institutional Review Board at the Urals Research Center for Radiation Medicine for approval.

**IX. Timetable for Long-Term Collaborative Epidemiologic Program (first 3 years).**

**A. East Ural Radioactive Trace Cohort**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
Tracing of Lost to Follow-up	Feasibility - 1 Year	Follow-up - 2 Years	
Coding & Computerization of Death Certificates	1 Year		
Verify Completeness of Cohort Born > 1957		2 Years	
Determine Availability of Cancer Morbidity	Feasibility - 1 Year	Abstract & Computerize	
Dosimetry (Project 1.1)	Calculate Collective Doses	Individual doses to selected target organs	
Unexposed Comparison Population	Feasibility - 1 Year	Data Collection/Follow-up	
Data Analyses		Power	Plan Analyses
Computerize Outpatient Records		2.5 Years	
		Data Analysis	

**B. Techa River Cohort**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
Determine Completeness of Cancer Morbidity	Feasibility - 1 Year	Abstract & computerize	
Cancer Morbidity for Kurgan Oblast	Feasibility - 1 Year	Abstract & computerize	
Validate cancer diagnoses		2 Years	
Computerization of data		2.5 Years	
Dosimetry (Project 1.1)		Individual doses to selected target organs	
Continue follow-up for mortality & morbidity			Continuous follow-up→
Data Analyses		Power	Plan Analyses
			Data Analysis

**X. Estimated Budget for URCRM**

**A. East Ural Radioactive Trace Cohort**

<b>DIRECT COSTS</b>		<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total</b>
<b>A. Personnel</b>	<b>Hours/Year</b>				
Principal Investigator	500	\$2,000	\$2,100	\$2,205	\$6,305
Project Coordinator	500	\$1,500	\$1,575	\$1,654	
Senior Researcher	1000	\$3,000	\$3,150	\$3,308	\$9,458
Data Base Manager	500	\$1,250	\$1,313	\$1,378	
Programmer	1000	\$2,500	\$2,625	\$2,756	\$7,881
Technician	1500	\$2,400	\$2,520	\$2,646	\$7,566
Technician	1500	\$2,400	\$2,520	\$2,646	\$7,566
Technician	1500	\$2,400	\$2,520	\$2,646	\$7,566
Coder/Nosologist	1500	\$3,300	\$3,465	\$3,638	\$10,403
Oncology Center Specialist	500	\$1,100	\$1,155	\$1,213	\$3,468
<b>Total</b>		<b>\$21,850</b>	<b>\$22,943</b>	<b>\$24,090</b>	<b>\$68,882</b>
Payroll Taxes (79%)		\$17,262	\$18,125	\$19,031	\$54,417
<b>Total Personnel</b>		<b>\$39,112</b>	<b>\$41,067</b>	<b>\$43,120</b>	<b>\$123,299</b>
<b>B. Equipment</b>					
Laptop Computer		\$2,300			\$2,300
Laser Printer		\$1,250			\$1,250
Scanner		\$650			\$650
Portable Copier		\$1,650			\$1,650
<b>Total Equipment</b>		<b>\$5,850</b>			<b>\$5,850</b>
<b>C. Travel</b>					
2 Trips/Year to U.S.		\$6,000	\$6,200	\$6,400	\$18,600
<b>D. Other</b>					
Office Supplies		\$600	\$600	\$600	\$1,800
Communications (Phone, Fax)		\$500	\$500	\$500	\$1,500
<b>TOTAL DIRECT COSTS</b>		<b>\$52,062</b>	<b>\$48,367</b>	<b>\$50,620</b>	<b>\$151,049</b>
<b>INDIRECT COSTS (40% of Personnel)</b>		<b>\$8,740</b>	<b>\$9,177</b>	<b>\$9,636</b>	<b>\$27,553</b>
<b>TOTAL</b>		<b>\$60,802</b>	<b>\$57,544</b>	<b>\$60,256</b>	<b>\$178,602</b>



**B. Techa River Cohort**

<b>DIRECT COSTS</b>					
		Year 1	Year 2	Year 3	Total
<b>A. Personnel</b>	<b>Hours/Year</b>				
Principal Investigator	500	\$2,000	\$2,100	\$2,205	\$6,305
Project Coordinator	500	\$1,500	\$1,575	\$1,654	\$4,729
Epidemiologist	1000	\$3,000	\$3,150	\$3,308	\$9,458
Epidemiologist	1500	\$3,750	\$3,938	\$4,134	\$11,822
Data Base Manager	500	\$1,250	\$1,313	\$1,378	\$3,941
Programmer	1000	\$2,500	\$2,625	\$2,756	\$7,881
Technician	1500	\$2,400	\$2,520	\$2,646	\$7,566
Technician	1000	\$1,600	\$1,680	\$1,764	\$5,044
Technician	1000	\$2,200	\$2,310	\$2,426	\$6,936
Technician	1500	\$1,800	\$1,890	\$1,985	\$5,675
Oncology Center Specialist	1000	\$2,200	\$2,310	\$2,426	\$6,936
<b>Total</b>		\$24,200	\$25,410	\$26,681	\$76,291
Payroll Taxes (79%)		\$19,118	\$20,074	\$21,078	\$60,269
<b>Total Personnel</b>		\$43,318	\$45,484	\$47,758	\$136,560
<b>B. Equipment</b>					
Laptop Computer		\$2,300			\$2,300
Laser Printer		\$1,250			\$1,250
Scanner		\$650			\$650
Portable Copier		\$1,650			\$1,650
<b>Total Equipment</b>		\$5,850			\$5,850
<b>C. Travel</b>					
2 Trips/Year to U.S.		\$6,000	\$6,200	\$6,400	\$18,600
<b>D. Other</b>					
Office Supplies		\$600	\$600	\$600	\$1,800
Communications (Phone,Fax)		\$500	\$500	\$500	\$1,500
<b>TOTAL DIRECT COSTS</b>		\$56,268	\$52,784	\$55,258	\$164,310
<b>INDIRECT COSTS (40% of Personnel))</b>		\$9,680	\$10,164	\$10,672	\$30,516
<b>TOTAL</b>		\$65,948	\$62,948	\$65,930	\$194,826

## **C. Budget Justification**

### **1. Personnel**

The roles of each of the key personnel from URCRM are described in Section VII, Collaborators/Collaborating Institutions. The technicians are needed to abstract, code and key enter data collected during the study. The Nosologist will code underlying cause on death certificates for the East Ural Radioactive Trace study. The oncology center specialists will assist in the collection of cancer morbidity information and in locating pathological materials for validation of diagnoses.

### **2. Equipment**

The laptop computers are necessary for recording information and preparing documents during visits to the oncology centers and other offsite locations to complete the tasks described. The scanners are necessary to preserve photocopies of death certificates, oncology records, and other records collected during the follow-up and diagnosis validation efforts. The portable copiers are necessary to photocopy death certificates and oncology records at offsite locations. The laser printers are necessary to print documents prepared during the course of the study.

## **XII. References**

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## **Appendix A - Urals Research Center for Radiation Medicine (URCRM) Hard Copy Information Inventory**

### **I. Archive Contents**

The Urals Research Center for Information ~~and Radiation Medicine (URCRM)~~ has collected radiation health effects data on inhabitants exposed to radiation incidents in the Southern Urals region of the Russian Federation. In particular, disease incidence, birth and mortality rates of exposed individuals were sporadically collected within different scientific and practical projects; therefore, its completeness varies. For example, death certificates were collected through 1992 for five districts of the Chelyabinsk Region affected by radiation incidents. For two districts of the Kurgan Region, death certificates were available only to 1982. Practically all birth certificates have been collected for children born to parents who were exposed to radiation from the Techa contamination who remained in the Chelyabinsk Region. Data for those exposed to radiation from the 1957 East Urals Radioactive Trace (EURT) are available to 1988. All hard copy information available at URCRM can be divided into one of the four groups listed below:

- 1. Unique information (only available at URCRM):**
  - outpatient medical charts
  - case histories
  - tissue sample logs
  - myelogram registration logs
  - radiochemical and dosimetric measurements card files
  - leukemia patient card files
- 2. Information for compiling registries collected by URCRM staff from different sources**
  - Techa registry card files
  - EURT registry card files
  - oncological patient card files
  - oligophrenia, schizophrenia, epilepsy and Down's syndrome patient card files
  - card files for patients with congenital defects and inherited diseases
  - registries of twins of the Kurgan Region
  - census logs of resettled population (late 1960's-1970's)
- 3. Registry information obtained from other organizations**
  - photocopies of resettled population lists
  - photocopies of tax books

4. **Background information for follow-up of migration, mortality and birth rates**

photocopied lists of people exposed to radiation (Mayak and Techa incidents) who received exposed population certificates  
handwritten copies and photocopies of death certificates  
handwritten copies of birth certificates

Table 1 (page B-3) summarizes the documents that form the URCRM archive.

An additional 4,000 photocopies of death certificates between 1983-1988 for two districts of the Kurgan Region were added to the URCRM archive. Also, 22 tax books archived in the Casley Regional Archive were photocopied. Lists of people who received exposed population certificates from social protection centers of five districts of the Chelyabinsk Region, seven metropolitan districts of the city of Chelyabinsk and regional social protection centers of the Chelyabinsk and Kurgan regions were also photocopied.

**II. Description of Archival Document Information Outpatient Charts**

Two types of outpatient charts included are individual outpatient charts (25 208 x 152 mm sheets), and a medical book ( 130 248 x 168 mm sheets). The cover sheet contains the patient's systemic number, last and first names and patronymic names, dates of birth, place of major exposure and current address. (Occasionally whole body counter measurement results are also included.) Doctor and other specialists record any changes on the charts while results of laboratory analyses and counts are attached to the chart.

**Table 1. Documents Forming the URCRM Archive**

<b>Number</b>	<b>Description</b>	<b>Quantity</b>
1	Outpatient charts including: EURT cohort; Techa cohort; Hematological; Miscellaneous	
2	Case histories (folders)	13,638
3	Tissue sample logs	9
4	Myelogram registration logs	7
5	Lifetime radiochemical and dosimetric measurements cards	~12,500
6	Card file for leukemia and chronic radiation sickness patients	~300
7	Techa registry cards	65,000
8	EURT registry cards	4,651
9	Oncological patients cards	17,100
10	Cards for oligophrenia, schizophrenia, epilepsy and Down's syndrome patients	3,976
11	Cards for patients with congenital defects and hereditary diseases	750
12	Kurgan Region twins registry (cards)	819
13	Census logs of villages with resettled populations	052
14	Photocopies of tax books	22
15	Photocopies of the following lists: - resettled population (according to Mayak data) - children in orphanages - prospecting parties	1,392 1,419 1,166
16	Handwritten copies and photocopies of death certificates for Chelyabinsk Region (Argayash, Krasnoarmeisk, Kunashak and Sosnovka Districts) and for Kurgan Region (Dolmatov and Kataisk Districts)	~107,000
17	Photocopied lists of people exposed to radiation (Mayak and Techa incidents) who received exposed population certificates	3,100
18	Handwritten copies of birth certificates	4,100



A formalized outpatient chart (FOC) contains the patient's passport data, place and dates of major exposure, previous addresses, current address, family history, diagnosis, and indexes of medical examinations. The outpatient charts are ordered by major exposure villages and within the villages by systemic numbers.

### **Case History for Hospital Patients**

Case histories are stored in 315 x 235 mm folders. The title page of the folders includes the archival number, the systemic number, and last, first and patronymic names. Case histories are enclosed on 36 sheets (293 x 210 mm, 20 mm thick). The title page of each case history has an archival number, annual registration number, last, first and patronymic names, date of birth and sometimes a current address. Also included in the case history are admittance and discharge dates, passport data, initial and final diagnoses, analysis and objective examination results, prescriptions, epicrisis, and the doctor in charge.

### **Tissue Sample Logs**

There are two sizes of tissue sample logs: (1) 125 sheets (295 x 200 mm), and (2) 60 sheets (375 x 275 mm). The log is designed for registration of osseous and hematopoietic tissues and trepanobiopsy. Included in this log are ordinal numbers, the patient's last, first and patronymic names, date of birth, systemic number, addresses (if available), date of sampling, preparation number and the analysis result.

### **Myelogram Registration Log**

The myelogram registration logs are in three sizes: (1) 500 sheets (210 x 294 mm); (2) 125 sheets (295 x 200 mm); and (3) 125 sheets (280 x 205 mm). These logs include ordinal number (general and from the beginning of the year), sampling dates, last, first and patronymic names, systemic number (if in the exposed population inventory), the year of birth, and analysis results.

### **Life-Time Radiochemical and Dosimetric Measurements Card File**

This card file contains 210 x 150 mm cards which include the systemic number, last, first and patronymic names, date of birth, gender, place and time of major exposure, date and results of whole-body counter measurements ( $^{137}\text{Cs}$ ,  $^{40}\text{K}$ , and  $^{90}\text{Sr}$  count in the whole body), forehead sensor measurement results, and  $^{90}\text{Sr}$  count in teeth. If radiochemical analysis of excretions was done, the type, the date of sampling and the analysis result are given.

## **Card File for Leukemia and Chronic Radiation Sickness Patients**

This card file is composed of 210 x 150 mm cards that includes last, first and patronymic names, systemic number, and place and time of major exposure. Occasionally, a relative's name and address may be given. Additional information listed on each card are last address, diagnosing year, year the patient's name was removed from the registry, blood count results, and whole body counter measurement results. If the person is dead of death, cause of death, and radiation dose are shown.

### **Techa Registry Card File**

The Techa registry card file is composed of 124 x 74 mm cards. Recorded in the top, left-hand corner are the last, first and patronymic names, closest relatives (mother, father and spouse) and their exposure locations corner. In the top, right-hand corner, the patient's former residences are shown by the year and place of major exposure and the year the patient was resettled or moved. The last entry is the patient's current address. The patient's date of birth and systemic number (in red ink) are written at the top center of the card. Information on the outpatient-patient medical examinations and the whole body counter measurements with their respective dates are given in the bottom left-hand corner.

### **EURT Registry Card File**

This card file is composed of individual 206 x 147 mm cards. The front top center contains the name of the settlement and the family number. The years the family lived in the village, taken from tax books, are written in pencil the top, right-hand corner. All the family members are listed on the card beginning with the head of the family with their date of births and dates of death. The availability of the death certificate is shown and the coded cause of death (according to International Classification of Diseases, Revision 9 - ICD-9). If a family member (or the entire family) moved to another village, the name of the new village and the year moved in, are also shown.

## **Card File for Oncological Patients**

The oncological patient card file is composed of individual 125 x 75 mm cards. Shown on the front of the card are last, first and patronymic names, systemic number (if the patient is part of an exposed population registry), diagnosis date, the diagnosis, vital status, and address.

### **Card File of Oligophrenia, Schizophrenia, Epilepsy and Down's Syndrome Patients**

The above card file is composed of individual 190 x 80 mm cards (for oligophrenia and schizophrenia patients) and 95 x 80 mm cards (for patients with Down's syndrome). The front of each card includes the last, first and patronymic names, year of birth, systemic number (if included in the registry of exposed people), address, diagnosis, obstetrical history, parental information (their last, first and patronymic names and years of birth).

### **Card File of Patients with Congenital Defects and Hereditary Diseases**

This card file is composed of individual 95 x 80 mm cards. The front of the card shows last, first and patronymic names, year and place of birth, systemic number (if on the registry of exposed population), parents' passport data, any diagnosis and medical examination results.

### **Kurgan Region Twin Registry**

The Kurgan Region Twin Registry consists of 205 x 150 mm cards. The front of the card includes the last, first and patronymic names of each twin, dates of birth, information about the parents including their systemic numbers (if in the registry of exposed population) and the place of major exposure.

### **Census Log**

The census log is a 125 page (207 x 300 mm) book. The title page includes the name of the village and the ordinal number. The population is listed by families with the head of the family noted and how other family members are related. Date of birth, previous addresses, current address and information about relocation are also shown in the census log. (Few logs contain alphabetized entries.)

### **Photocopies of Tax Books**

These tax books were photocopied on 210 x 297 mm paper then bound into books. Labels show the name of the village, census year, streets and the district archive in which the book was photocopied. The first page is a photocopy of the original title page of where the village or the village council is shown, years of completing the book, the ordinal number originally assigned in the village in the year the census was started, and the street where the census was taken. Each photocopy contains information about the head of the family and all the family members with their last, first and patronymic names, date of birth, date of death,

ethnic identity, education, social status, moving information, military service, and education.

### **Resettled Population List (Techa Contamination)**

This list is formatted on 302 x 222 mm paper. On the title page, villages are listed by districts and regions. Each entry has an ordinal number, the resettled person's last, first and patronymic names, and number of family members. The amount of monetary compensation, the availability and place of archiving the estimated value of the family personal belongings are also included.

### **Resettled Population List (MAYAK Accident)**

Formatted on 306 x 222 mm paper. this list shows settlements on the title page by districts and regions. Each entry has an ordinal number, last, first and patronymic names of the resettled person. year of birth, job affiliation and position at the time of resettlement. availability and place of archiving of the estimated value of the family and personal belongings.

### **List of Children in Orphanages**

On 295 x 210 mm paper, this list shows the name of the orphanage and the year the list was compiled on the title page. The list also shows last, first and patronymic name, year a child moved to an orphanage, when a child was moved, and the name of the new orphanage.

### **Copies of Death Certificates**

There are two types of death certificate copies: handwritten and photocopies. There are four types of handwritten copies of death certificates:

1. Formatted on 150 x 150 mm paper these death certificates include ordinal or systemic number (if the patient's name is in the registry of exposed population), last, first and patronymic names, date, cause and coded cause of death, last address (if there is a systemic number, the place of major exposure), a doctor's or paramedic's statement, and informant.

2. These death certificates are formatted on 210 x 145 mm paper and include the ordinal or systemic number (if the patient's name is included in the registry of exposed population), last, first and patronymic names, date of birth, date of and death, gender, systemic number, place of major exposure, place of death, informant (autopsy record, death certificate, and so forth), cause of death, and coded diagnosis.
3. Formatted on 300 x 220 mm paper these death certificates contain ordinal or systemic number (if the patient is included in the exposed population registry), last, first and patronymic names, date of birth, date of death, gender, and if there is a systemic number, places of major exposure, place of birth, place of death, education, employment, sources of information (autopsy record, death certificate or other), the cause of death, coded diagnosis, and informant.
4. These death certificates are formatted on 190 x 805 mm paper that include systemic number (if the patient is included in the exposed population registry), last, first and patronymic names, date of death, cause of death, coded cause of death, and the last address.

Photocopies of death certificates are on 210 x 297 mm sheets. Each photocopy contains the ordinal number, last, first and patronymic names, ethnic identity, date, place and cause of death, date and place of birth, place of permanent residency, marital status, job affiliation and profession, education, death statement, the informant's last, first and patronymic names and address.

### **Exposed Population Certificate List**

Photocopies are made on 210 x 297 mm paper. The seal of the district administration head where exposed population certificates were issued is imprinted on the top right-hand corner along with his signature and the date. The name of the village in which the patient lived at the time of the accident is shown in the middle of the page. The list contains last, first and patronymic names, date of birth, the period lived in the village and evacuation period, the certificate serial number and date of issue, on what basis it was issued, current address and signature. Shown at the end of each list is the seal of the manager of the social protection center and his signature along with the signature of a specialist of the same center where the certificate was issued.

## **Birth Certificate Copies**

Copies of birth certificates are individual handwritten cards (190 x 80 mm). Each card has the last, first and patronymic names, place and date of birth, last, first and patronymic names of the patient's father and mother with their systemic numbers.

### **III. Sources for Updating Information**

The information system is updated when a patient visits the outpatient department of the URCRM. The receptionist asks the patient about his passport data, when he lived on the Techa, his current address, education, job affiliation, job exposure, and risk factors. The patient is also asked about family history (parents, siblings, spouse and children). An FOC is completed as a result and if the information has already been entered, it is verified and updated. An oncological screening form is also completed.

The patient is then analyzed in the clinical laboratory where he also undergoes measurements by the whole body counter. Women are required to see a gynecologist for an examination. The gynecologist then completes the pertinent sections of the FOC (gynecological status, pregnancy and child birth) and the oncological screening form. The patient is also examined by another doctor who enters the diagnosis on the FOC diagnosis section. If the patient is hospitalized, the doctor in charge completes this section.

Medical examinations of the populations of the five districts of the Chelyabinsk Region and the two districts of the Kurgan Region are regularly completed by URCRM staff. Queries, similar to those used when the patient visits the outpatient department, are also completed during these examinations. Information, therefore, is annually updated for ~4,000 people because of visits to the outpatient department and through local medical examinations.

To follow global indexes as migration, death and birth rates, it was decided information will be collected regularly through regional addresses and ZAGS offices. Another source of information are tax books for villages whose population was evacuated. In addition, a 1994 law was enacted on the social protection of radiation-exposed population because of an accident at PA MAYAK and on account of a radioactive release into the Techa. Because of this law, issuing certificates to exposed populations began.

The criteria for determining what populations would receive these certificates is described below.

### **Chelyabinsk Region**

1. People presently living in villages of the five exposed districts (in district social protection offices).
2. People presently living in the city of Chelyabinsk (in seven metropolitan district social protection offices of Chelyabinsk).
3. People who lived in the contaminated area of the Chelyabinsk Region and who presently live in other districts and towns of the Chelyabinsk Region and outside the Chelyabinsk Region (in the regional protection office).

### **Kurgan Region**

1. People who lived in the contaminated area of the Kurgan Region (in the regional office of social protection).

### **Sverdlovsk Region**

1. People who lived in the EURT evacuated villages (in the EURT Administration).

After evaluating our resources and the significance of the information collected for research and practical activities carried out by other departments of URCRM, we collected the following information.

### **Migration**

Lists of people who received exposed population certificates (Techa or Mayak incidents) were photocopied in the respective offices of the Chelyabinsk and Kurgan Regions. An electronic copy of such lists was received from the Sverdlovsk Region.

### **Mortality Rate**

Death certificates for the years 1983-1989 were photocopied for two contaminated districts of the Kurgan Region.

### **Refining EURT Registry**

Tax books for villages exposed to the 1957 radiation release (stored in the Casley archive) have been photocopied.



## **Appendix B - URCRM Data Base**

### **I. Description of the Data Base**

Currently, there is a Unified Information Data Base (DB MAN) available. The DB MAN is a relational type data base and it consists of individual indexed relations integrated through relationships from primary and secondary keys. The main keys, which relate the registries, are systemic numbers. The systemic numbers are unique and have error protection coding. For example, if a patient is assigned a wrong systemic number (the same person is assigned two different systemic numbers and is listed twice) and the error is detected, one number is permanently deleted. (The DB MAN registries and their relationships are shown in Figure 1.)

#### **Identification Registry**

The Identification Registry is the core of the DB MAN. It contains a set of attributes characterizing each individual and its association with radiation situations on the Techa and in the EURT area.

#### **Strontium Registry**

The results of the  $^{90}\text{Sr}$  measurements in the whole body, teeth, frontal bone, and urine are stored in the Strontium Registry.

#### **Diagnosis Registry**

The Diagnosis Registry was formed based on the results of many years of medical examinations.

#### **Family History Registry**

The Family History Registry includes information from tax books and FOCs arranged by family cells. This registry is necessary for evaluating individual dose loads by the method of "family ecology" and for estimating genetic risk. It includes systemic numbers, relationship codes, and the systemic number of a relative. The registry is supplied with a program of data entry analysis. For example, if entry of a child's first or patronymic name is incorrect, the computer alerts the user.

## **Dead People Registry**

This registry includes first and last names, date of birth, date of death, place of death, and cause of death for five districts of the Chelyabinsk Region (Argayash, Casley, Krasnoarmeysk, Kunashak, and Sosnovka) and two districts of the Kurgan Region (Dolmatov and Kataisk). It also contains information for the people exposed to radiation because of the Techa contamination and the 1957 accidents, and the control group (people who were not exposed to radiation in these incidents but lived in those districts).

## **Other Information**

Besides the main registries the computer data base includes the following information:

- cancer registry
- peripheric blood count
- biochemical blood count
- immunological data
- neurological status
- physical development
- everyday life risk factors
- occupational risk factors
- job affiliation
- gynecological history
- pregnancy history
- therapeutic status

## **II. Completion and Correction of Data Base**

### **Identification Registry**

As part of this project, all of the registry information (except the current address) was verified and corrected using reference books of first and last names and settlements that made it possible to maintain random error protection. This was possible because of a new computer program called "Patient Identification" which was developed with an ongoing project of the URCRM Biophysical Laboratory entitled "Improvement of the Unified Information System "Radiation Situation and Population Health in the Area of PA Mayak."

Code reference manuals are presently used for data entry control. This eliminates data entry errors and their redundancy, therefore, speeding up data entry. It also ensures information reliability and eliminates inconsistencies. When encountering the problem of reading the person's last and first names (especially if the person is a Tartar or a Bashkir), the operator can use the reference book and enter the verified information in the registry. The code reference book of exposed settlements makes it possible to enter information for only seven districts under investigation. Such lines as status, status year and cohort are protected from arbitrary entry by the following phrases: alive because somebody said so, dead because somebody said so, or dead with a certificate. The date of the end of the period a person lived in a village is limited by the year of relocation. For example, if the person lived in Metlino, the reference value list "will not allow" to record any year following 1956.

### **Strontium Registry**

Information for this registry is entered, checked and corrected by the staff of the URCRM Biophysical Laboratory. To do this, a computer program, "Whole Body Counter Operator," was developed.

### **Diagnosis Registry**

The URCRM Epidemiologic Department is responsible for diagnosis coding, data entry and correction. To do this work, a computer program "Diagnosis" was developed. Information for this registry is taken from all outpatient cards of the URCRM reception office by the diagnoses shown. The diagnosis reference book is a computerized version of the International Classification of Diseases, Revision 9 (ICD-9).

This registry has information for all people born in 1949 and prior for all the villages of the Chelyabinsk Region being studied. Information for progeny is introduced for Asanovo, Ibragimovo, Isayevo, Kurmanovo, S. Taskino, Metlino, Muslumovo, Nadirov Most, Nadirovka, and Techa-Brod.

## **Family History Registry**

Three URCRM subdivisions are responsible for data entry, its checking and introducing corrections:

1. DB Information Support Group
2. Biophysical Laboratory
3. Epidemiologic Department

A computer program "Genealogy" was developed in the URCRM Biophysical Laboratory to support this task for the ongoing project "Improvement of the Unified Information System Radiation Situation and Population Health in the Area of PA Mayak." Information is added to this registry from archival materials (outpatient charts, the Techa Registry card file, and the EURT Registry card file). Information is introduced by settlements where the patient was exposed to radiation. This registry has been completed for the following settlements: Asanovo, Gerasimovka, Ibragimovo, Isayevo, S. Taskino, Metlino, Muslumovo, Muslumovo (railway station), Nadirov Most, Nadirovka, Osolodka, Panovo, Geologorazvedka, Techa-Brod, and Cherepanovo.

## **Death Registry**

The Data Base Information Support Group and Epidemiologic Department staff are responsible for coding causes of death, data entry and introducing corrections. There is a computer program entitled "Patient Identification" for this purpose. The verification of the dead people registry has been started. Verification of 81% (12,222 cases) of the population exposed to radiation on the Techa (Techa Registry) has been completed.

## **Other Information**

The computerized data base has a 12-file structure (see Section I). The information (except the Cancer Registry) is updated from FOCs in a semiautomatic mode when the patient visits the URCRM Outpatient Department. The Cancer Registry includes information on 18,057 patients of the Chelyabinsk and Kurgan regions obtained from the regional oncological centers (first and last names, date of birth and date of diagnosing the tumor and its type). It is updated by the Epidemiologic Department staff in a semiautomatic mode.

### III. Computerized Data Base Status (through December 1995)

Information on the main registries of the data base is summarized in Table 1. The registries were completed (Section II) and all available data (passport and residence information) have been included in the Identification Registry. The current address information is 80% complete. The Strontium Registry (100% complete) is automatically updated when the patient undergoes dosimetric measurements. The Family History Registry is 44% complete while the completeness of the "Diagnosis" and the "Dead People" registries have not been determined. Information transfer from archival documents to the Registry Diagnosis has not been completed. Not all death certificates (Death Registry) have been collected for two districts of the Kurgan Region (since 1983) and for the Chelyabinsk Region (since 1993). (Table 2 contains modification information introduced into the data base other files.)

Table 1. Status of the Main Registries

No.	Registry	Number of Records	Percent Verified
1	Identification:		
	- passport data	90,945	100
	- places of exposure	87,974	100
	- last address	58,355	not verified
2	Strontium	53,475	100
3	Diagnosis	160,789	100
4	Family History	39,544	100
5	All deceased including:	110,675	
	- Tcha Registry	15,029	81
	- EURT Registry	4,542	not verified

Since death certificates were no longer collected for two districts of the Kurgan Region, there is a sharp decrease in death information in the Techa cohort. Photocopying of death certificates organized in the Kurgan Regional ZAGS will allow more accurate information. Organizing death certificate collection for the Chelyabinsk Region beginning with 1993 and every year after is also necessary. As mentioned above, we are planning to organize a regular collection of mortality data from regional ZAGS archives. A significant amount of death information was obtained from relatives that create problems in correlating risk of death with exposure level. We are planning, therefore, to search for death certificates of deceased individuals whose relatives have verified are dead.

**Table 3. Amount of Information in Data Base Other Files**

No.	Records	Number of Records		Data Changes for Two Years
		Dec. 1993	Dec. 1995	
1	Cancer Registry	13,940	18,057	4,117
2	Peripheral Blood Count	45,013	50,427	5,424
3	Biochemical Blood Count	4,538	4,538	0
4	Immunological Data	621	1,906	1,285
5	Neurological Status	4,693	7,383	2,690
6	Physical Development	17,730	17,732	2
7	Risk Factors: everyday Life	11,050	11,444	394
8	Occupational	10,114	10,433	319
9	Job Affiliation	12,302	12,603	301
10	Gynecological Status	930	930	0
11	Pregnancy History	6,577	6,577	0
12	Therapeutic Status	7,351	7,609	258

Figure 1. Data Base "MAN"

**III. Identification Registry**

1. Systemic Number
2. Gender
3. Last Name
4. First Name
5. Patronymic
6. Ethnic Identity
7. Place of exposure (Techa, EURT)
8. Date of birth
9. Places & dates lived in place of exposure
10. Last known address

**II. Diagnosis Registry**

1. Systemic Number
2. Examination Date
3. Examination conditions (field, outpatient department, hospital)
4. Diagnosis (ICD-9)

**I. Registry of Measurements of Radioactivity in the Whole Body**

1. Systemic Number
2. Measurement Date
3.  $^{137}\text{Cs}$  Count
4. K Count
5.  $^{90}\text{Sr}$  Count
6.  $\beta$ -activity of teeth
7.  $\beta$ -activity of frontal bone

**IV. Family History Registry**

1. Systemic Number
2. Father
3. Mother
4. Spouse
5. Siblings
6. Children

**V. Dead People Registry**

1. Systemic Number
2. Date of Death
3. Age at Death
4. Education
5. Profession
6. Source of information about death
7. Cause of Death (ICD-9)

## Appendix C - Curriculum Vitae

**Name:** Mira M. Kossenko  
**Birth Date:** 16 January, 1937  
**Birth Place:** Magnitogorsk, Russian Federation  
**Citizenship:** Russian Federation  
**Marital Status:** Married

### Education:

1983 Radiation Special Course for heads of Radiation Medicine Departments, Moscow, USSR  
1973 Clinical Special Course at the Advanced Medical Training Pharmacology, Moscow, USSR  
1966 Internal Diseases Department Medicine, Chelyabinsk Medical Institute, Chelyabinsk, USSR  
1961 M.D., Chelyabinsk Medical Institute, Chelyabinsk, USSR

### Employment:

1991 - Present Head, Epidemiology Laboratory Urals Research Center for Radiation Medicine (formerly Branch Number 4, Institute of Biophysics) Chelyabinsk, Russian Federation  
1986 - 1987 Scientific Advisor on Chernobyl problems, Byelorussia and Ukraine Health Ministries  
1983 - 1986 Head, Clinical Department, Urals Research Center for Radiation Medicine, Chelyabinsk, USSR  
1967 - 1983 Researcher, Clinical Department, Branch 4, Institute of Biophysics, Chelyabinsk, USSR  
1966 - 1967 Clinician, Department for radiation Exposed People Chelyabinsk, USSR  
1961 - 1964 Family physician, Family Doctor Service System, Chelyabinsk, USSR